NO. 88-704

SUPREME COURT, U.S.
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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1988

IN RE: BENDECTIN LITIGATION

SARAH ANN HOFFMAN, ET AL.
ELIZABETH ANN DAVIS, ET AL.
AND SHANE ROSS WOOD, ETC., ET AL.
Petitioners

vs.

MERRELL DOW PHARMACEUTICALS INC.
Respondent

BRIEF FOR RESPONDENT IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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CORPORATE AFFILIATIONS OF RESPONDENT

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I. STATEMENT OF THE CASE

A. ORIGIN AND FILING CHRONOLOGY OF THE BENDECTIN CASES IN ISSUE

The Petitioners were plaintiffs in the U.S. District Court for the Southern District of Ohio, Western Division, in a consolidated trial that resulted in a verdict and judgment for the Respondent, Merrell Dow Pharmaceuticals Inc. They seek review of the decision of the U.S. Court of Appeals for the Sixth Circuit, to the extent to which it affirmed the defense judgment of the district court. The consolidated trial concerned claims that approximately 1160 children (of whom 82 were deceased at time of trial) were afflicted with birth defects as a result of their mothers' ingestion, during pregnancy, of Respondent's pharmaceutical product, Bendectin.

Some eight hundred Petitioner families filed their claims in federal court in Ohio.[1] The remaining Petitioner families, after transfer of their cases to the Southern District of Ohio for discovery by the Judicial Panel for Multidistrict Litigation, voluntarily sought consolidation for trial in Ohio.

The fact that the Petitioners are so numerous results, in large part, from the district court's decision of April 12, 1984, pursuant to Rule 42(b), Fed. R. Civ. P., to initially try the question whether Bendectin, taken by a human mother in therapeutic doses during the period of embryonic organogenesis (the period of gestation during which the organs are formed) causes human birth defects. This was the so called "trifurcation order." The streamlining effect which it had on initial trial preparation caused the Ohio litigation to become a nationwide magnet for *new* Bendectin plaintiffs, seeking consolidation with the pending federal action. To

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[1] 72 lawsuits involving 147 children were filed in state court in Ohio, and subsequently removed to federal court. All but 21 of those children were also plaintiffs in parallel suits filed originally in federal court. Such duplicative filings introduce some uncertainty into Respondent's estimates of the number of Petitioners in each category.

understand the benefits of the procedure which the district court chose requires an appreciation of issues which arise in the more routine trial of an individual Bendectin case.

Birth defects are, unfortunately, a relatively common occurrence, being seen in approximately 3 to 7 percent of births. The causes of most birth defects (around eighty percent) are unknown. In the occasional instance, the cause can be identified as genetic, environmental or as the ingestion by the mother of some injurious agent. Bendectin was a widely used prescription medicine for alleviation of nausea and vomiting in pregnancy. It has been used since 1956 in some 18 million pregnancies in the United States alone. Its wide usage over so many years made it inevitable that many women who had taken Bendectin would by chance deliver babies with birth defects, merely as a reflection of background incidence. Bendectin is and has been approved by the FDA since 1956, and has been the subject of intense published scientific study concerning its safety for the unborn child.

The "trifurcated" causation trial postponed (and ultimately eliminated) the need to consider certain plaintiff-specific causation issues. These include the following:

1. Did the mother actually take Bendectin? — While complaints invariably allege the ingestion of Bendectin during pregnancy, the medical records of the mother or baby sometimes contradict this contention, reporting the absence during pregnancy of "morning sickness" (the sole affliction for which Bendectin was indicated) or specifically recording that no medication was taken during pregnancy. Since Bendectin is a prescription medicine, lack of any physician or pharmacy records of a prescription is evidence of non-ingestion.

2. If the mother took Bendectin, did she take it during the criticial period of pregnancy? — Sometimes a plaintiff mother reports a first ingestion of Bendectin at a point in pregnancy by which it is scientifically demonstrable that the deformity with which her child is afflicted was already present. This circumstance has resulted, in some cases, in summary disposition.

3. Is there a genetic cause for the birth defect? — Some birth defects are caused by specific chromosomal or genetic characteristics of the parents. Detection of these factors requires a genetic examination and evaluation of the parents and child and collection of information regarding family history.

4. Was the mother exposed to some known teratogenic[2] agent? — Approximately twenty-five substances are recognized as human teratogens.

None of the foregoing inquiries would answer the broader question whether Bendectin, used as directed, causes human birth defects. However, each Petitioner was obliged to demonstrate the affirmative of such question by a preponderance of the evidence. Evidence on the issue is voluminous, detailed and technical.

"Trifurcation" of the causation issue was appealing to plaintiffs for several reasons. It permitted pooling of counsel's talents and plaintiffs' resources. Late-arriving plaintiffs could "coat tail" on the trial preparation of a small group of plaintiffs' lawyers who had managed trial preparation from the beginning. The stay on discovery (discussed below) would forestall development of the facts in individual cases and postpone the associated discovery burdens of plaintiffs and their individual counsel. A plaintiffs' victory in the initial trial would dramatically advance prospects for a favorable settlement for any plaintiff *whose case had been consolidated.*

New plaintiffs flocked to join the "trifurcated" lawsuit. Some successfully sought consolidation while the trial was actually underway. The trial was originally scheduled for June 11, 1984. However, Respondent negotiated a tentative settlement agreement with plaintiffs through the Plaintiffs' Lead Counsel Committee (PLCC), a panel of five attorneys elected from their numbers by plaintiffs' counsel to prepare and try

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[2] Dorland's Illustrated Medical Dictionary, 24th Edition, defines a "teratogen" as: "an agent or factor that causes the production of physical defects in the developing embryo."

the case. On June 18, 1984, the district court issued an order certifying a Rule 23(b)(1) non-opt-out class of plaintiffs for settlement purposes, an essential element of the settlement. Certain plaintiffs took exception to the settlement agreement and shortly secured a writ of mandamus from the Sixth Circuit Court of Appeals vacating the order certifying the settlement class.[3]

While the settlement was pending, Petitioners successfully sought a stay of all further discovery for 120 days, to expire on December 28, 1984. Petitioners thereafter sought a stipulated extension of the discovery stay until July 1, 1985, long after the anticipated completion of the initial phase of trial, then scheduled to begin in February 1985. Respondent, in light of the circumscribed nature of the initial "trifurcated" trial, (and at Petitioners' request) agreed to forego any discovery prior to the first stage of trial, regarding the claims of the 561 Petitioner families who joined the consolidated suit after discovery was first stayed.

The "trifurcation" order permitted the number of plaintiffs to more than triple before trial, without either delaying that trial or enlarging the proof to be offered by either side. Of plaintiff families who filed their Bendectin claims in Ohio federal courts after the issuance of the order of trifurcation, more than 400 were represented by one or more members of the PLCC.

All Petitioners who had sued in federal courts outside Ohio were, *after* trifurcation was ordered, given the choice whether their cases would be remanded for disposition to the districts of origin or consolidated for the "trifurcated" trial. Each declined the district court's offer of a remand to their originally chosen federal district.[4] Thus, more than eight hun-

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[3] The abortive settlement was not a major factor in attracting new plaintiffs. Only 84 Petitioners filed suit in the district court while it was pending.

[4] Numerous other plaintiffs declined to participate and their cases were remanded to their districts of origin for the individual disposition which Petitioners now maintain was unlawfully denied them.

dred either accepted consolidation without objection after the trifurcation order was entered or declined the opportunity for remand.[5] If any Petitioner was dismayed by the trifurcation order or considered such a trial format unfair, the secret was well kept from the hundreds of additional plaintiffs who joined thereafter, mostly represented by PLCC members.

B. THE "TRIFURCATION" ORDER: DOES BENDECTIN CAUSE BIRTH DEFECTS?

The verdict consisted of the jury's negative answer to a special interrogatory under Rule 49, Fed. R. Civ. P. "Have the Plaintiffs established by a preponderance of the evidence that ingestion of Bendectin in therapeutic doses during the period of fetal organogenesis is a proximate cause of human birth defects?" This ended the trial. The district court, on March 12, 1985, entered a judgment for the Defendant.

The concept of a separate trial on the threshold question whether Bendectin causes birth defects originated long before. At a status conference on July 1, 1983, the Chairman of the PLCC proposed trying 15 to 20 selected cases on the common issue of causation:

> We would try on the common issue of causal connection, is this a teratogen, and once we had a result as to those cases, we could then branch out, and as far as I am concerned, Your Honor, once liability, if it's not established, we are over. If it is established, then the damage thing can be done in some kind of other concept of funds for different groups of persons.

Transcript of Status Conference of July 1, 1983.

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[5] As their numbers grew, plaintiffs several times sought reconsideration of the trifurcation order but, except for certain plaintiffs in transferred cases, no Petitioner ever objected to the *consolidation* of his suit for trifurcated trial. The later-arriving plaintiffs clearly wished to preserve a claim of error notwithstanding their judgment that this arrangement was perferrable to their other litigation options.

Soon after, in a memorandum dated September 29, 1983, the PLCC suggested, among other issues suitable for a consolidated trial: "Whether Bendectin is teratogenic." They further wrote:

> But since, as the court recognizes, success upon one or more of the following issues is "essential to the success of any Plaintiffs' claim" consolidated trial upon these issues could accomplish a great savings of time and effort and avoid needless repetitive litigation . . . Should the Plaintiffs succeed upon any one of these enumerated issues, then the actions could proceed individually upon issues related to individual cases. In this manner, the interest of convenience and economy Rule 42 is designed to promote would be served.

Plaintiffs' response to court's order to show cause.

On December 29, 1983, the district court issued an order listing the common issues which would be tried in the consolidated cases beginning June 11, 1984. This was amended on April 12, 1984. The court stated, in part:

> The trial of this matter on liability issues will be trifurcated and questions relating to causation will be considered first. A jury determination on such issue will be made before any other matter is considered. Should Plaintiffs prevail on causation issues, the jury will hear and then consider the other matters listed herein. A Defendant's verdict on the issue of causation will terminate the trial.[6]

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[6] The earlier order had included the issues whether Bendectin was "unreasonably dangerous" and of the adequacy of warnings provided by Respondent. These questions clearly required a threshold finding of what "danger," if any, existed.

C. THE DISTRICT COURT'S ORDER EXCLUDING FROM THE COURTROOM CERTAIN MINOR PARTIES IN INTEREST

The district court, on February 19, 1985,[7] after the trial was underway, journalized an order precluding children with visible deformities and those under 10 years of age from being present in the courtroom. The court had been extensively briefed as to the different types of birth defects in issue and had, in December, 1983, been provided with a list of birth defects alleged by those plaintiffs who were then before it. The trial court reserved, within the courthouse, a room equipped with closed circuit television. (Appendix to Petition, page 67a) By this means, any children who wished to witness the trial could do so with their parents or other care givers. Telephone communications were established between the television viewing room and the PLCC in the courtroom. Representatives of plaintiffs' counsel were to be present in the viewing room to assist in any attorney-client communications which were desired. No parent or guardian of a minor plaintiff was affected by the exclusion order, nor was any minor plaintiff who was not within its terms.

The record does not show which children who were described by the order would otherwise have attended the trial. Petitioners' counsel made no move to argue that specific children could attend the trial without danger of prejudice or

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[7] The written exclusion order preceded by 6 days a public event which became known as "Bendectin Justice Day." This was a march to and around the federal courthouse in Cincinnati by a number of families including children with birth defects. Having learned that this event was in the offing, the district court ordered the jury sequestered from Sunday afternoon, February 24, 1985 until Wednesday, February 27. The demonstration occurred on Monday, February 25 and was, that morning, discussed by the court with counsel. Petitioners' counsel requested that the jury be told that they, the attorneys, were not responsible for the demonstration. The court declined to inform the jurors as to the cause of the sequestration order but only advised them that they were not physically endangered. At best, this episode confirms that not all claimants were under their counsel's direction or were inclined to let the jury decide the case solely on the evidence.

disruption. The emphasis of argument was that the order was erroneous, not that it was overbroad. Including the adult plaintiffs, the trial involved between 2000 and 3000 plaintiffs. It was always clear that most of these people would not attend the trial.

In March 1984, the district court, noted that its courtroom could accommodate no more than 100 plaintiffs' attorneys and 50 plaintiffs. Counsel were directed to promptly advise the court if additional space would be required. The population of plaintiffs was then less than one-third what it would be by trial. At one point, the district court discussed the possibility of renting the Cincinnati Convention Center, if necessary, to accommodate those wishing to attend. Nonetheless, Petitioners' counsel never advised the court that the normal courtroom would be inadequate. Obviously few plaintiffs, adults or children, wished to follow the trial in person from day to day.

On March 19, 1984 (when only about 260 Petitioners had filed their suits in federal courts in Ohio), the district court orally disclosed its intention to exclude from the courtroom children who were "not of an age where that child can meaningfully communicate with a lawyer and assist in the trial. . ." In response, one member of the PLCC suggested that the court select *at random* five children possessing birth defects from each of eight categories of birth defects in issue.[8]

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[8] These categories were:

a) limb defects
b) other muscular/skeletal defects
c) central nervous system defects
d) heart defects
e) head deformities
f) respiratory defects
g) gastrointestinal defects
h) genital urinary defects
i) death

Of the eight categories involving living children, only categories a, b, and e clearly suggested that such defects might be *visible*. Of course, the exclusion order is irrelevant to any case involving a deceased child.

Only these children would attend the trial. While the court declined this suggestion, the proposal revealed that no importance was attached to attendance at trial by any particular minor plaintiff.

D. HISTORY OF THE JURISDICTIONAL ISSUE

Of those roughly two hundred Petitioners who are situated to present Petitioners' third question of law, (because they were, at the filing of their suits in federal court, of nondiverse citizenship with Respondent) the earliest case was filed in 1981 and the last (involving 7 Petitioners) was filed and voluntarily consolidated when the trial, itself, was halfway to completion. On March 12, 1985, a jury verdict for the Respondent was rendered and a judgment entered accordingly. On March 22, 1985, Petitioners filed a motion for a new trial and other relief.

On July 15, 1985, before Petitioners' motion for new trial had been ruled upon, the court of appeals issued its decision (discussed hereinafter) in two cases brought by other Bendectin plaintiffs, *Thompson* v. *Merrell Dow Pharmaceuticals Inc.* and *McTavish* v. *Merrell Dow Pharmaceuticals Inc.*, 766 F.2d 1005 (6th Cir. 1985). Pursuant to that opinion, the district court, *sua sponte* on August 27, 1985, issued an order for the dismissal or remand of 300 Bendectin cases filed in the district court or removed from Ohio state courts wherein plaintiffs were citizens of Ohio.[9] On August 30, 1985, before the dismissal/remand order by the district court had been implemented, Respondent moved for a stay of that order to per-

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[9] Respondent believes that the district court initially drew the erroneous conclusion that the Sixth Circuit in *Thompson* had *ruled* that the FDCA permits no private claims and that Petitioners' *federally-filed* complaints alleging such private claims could not support jurisdiction. As noted hereafter, neither the Sixth Circuit nor this Court made such ruling in *Thompson*. The district court never issued any decision on its reconsideration of the jurisdictional issue because the Petitioners' appeal placed this issue before the court of appeals.

mit briefing of the jurisdictional issues. On September 3, 1985, the district court granted the requested stay, effectively agreeing to reconsider the order. On September 17, 1985, with the stay of the dismissal/remand order still in effect, the district court denied Petitioners' motions for new trial and JNOV. On October 11, 1985, Petitioners filed their notice of appeal to the Sixth Circuit.

On October 11, 1985, Respondent filed with this Court its petition for certiorari to the Sixth Circuit in the *Thompson* case. Two questions were presented by that petition:

1. Where a plaintiff alleges that a violation of a specific federal regulatory statute constitutes a rebuttable presumption of negligence and that such a violation directly and proximately caused injury to plaintiff, does such claim "necessarily depend" on resolution of an issue of federal law, so as to vest subject matter jurisdiction in the District Court?
2. Where a claim which "necessarily depends" on resolution of an issue of federal law is joined with other claims of purely local law which would, if the plaintiff prevails, obviate the federal question, does the pendency of such purely local claims deprive the District Court of jurisdiction?

On December 2, 1985, this Court granted Respondent's petition for certiorari in *Thompson*. *Merrell Dow Pharmaceuticals Inc.* v. *Thompson*, 474 U.S. 1004 (1985). The district court had not yet ruled on the arguments of the parties concerning that court's *sua sponte* order of August 27, 1985 dismissing or remanding the 300 cases. Petitioners and Respondent had briefed the issues and the stay of the dismissal/remand order was still in effect. Respondent had briefed certain grounds for federal subject matter jurisdiction (hereafter discussed) which were not within the grant of certiorari by this Court in *Thompson*, but which would, as it maintained, independently sustain subject matter jurisdiction over the 300 cases.

On January 6, 1986, the district court modified,[10] in part, its dismissal/remand order of August 27, 1985, but continued the stay of its order of August 27, 1985 as to the great majority of the 300 cases. Thereafter, the court of appeals reversed that order as to federally-filed cases, but left undisturbed the remand portion of the order.

II. SUMMARY OF ARGUMENT

Petitioners, themselves, suggested that the question whether Bendectin causes birth defects was appropriate for a consolidated trial, and that such a trial could significantly advance the litigation. Though always protesting "trifurcation" of the case, new plaintiffs rushed to join the litigation, obviously anticipating success rather than fearing any perceived unfairness in the trial format. Petitioners were pleased to join forces to show that Bendectin was injurious, but now claim that it was unfair that they were forbidden to bolster their inadequate scientific evidence by vilifying the Respondent before the jury. The district court's decision to first try the most difficult common issue of all the cases was a sound exercise of discretion in a case in which emotional appeals might easily have overcome the evidence.

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[10] As to certain cases among the 300, the district court ruled that reconsideration need not await the decision of this Court in *Thompson*. The district court ruled that the cases of Michael Huseman, U.S.D.C. No. C-1-85-0692, and Shawn Beggs, U.S.D.C. No. C-1-85-0717 had previously been voluntarily dismissed with prejudice by the plaintiffs and were erroneously included in the August 27 order. A similar ruling was made with respect to the case of Elizabeth Newman, U.S.D.C. No. C-85-0716. As to the case of Kelly Mullanney, U.S.D.C. No. C-85-512, the district court determined, per *Grubbs* v. *General Electric Credit Corp.*, 405 U.S. 699 (1972) that diversity of citizenship was an adequate basis for jurisdiction. Likewise in Kimberly Wykoff, U.S.D.C. No. C-82-1039, Robbin E. Thomas, U.S.D.C. No. C-1-81-0069, Irving Rosenstein, U.S.D.C. No. C-1-82-0964 and Troy Hill, U.S.D.C. No. C-1-82-0224, the court noted that diversity of citizenship existed when the complaints were filed. These cases were, accordingly, removed from the list of cases to be dismissed for want of subject matter jurisdiction.

Certain Petitioners (who are unknown and unidentifiable) claim that the district court's order excluding small children and deformed children from the courtroom denied their rights of due process in the trial of their claims. Such Petitioners, nonetheless, declined to offer evidence of their individual circumstances because such details were irrelevant to the issue then on trial. Even those excluded from the courtroom had as full an opportunity to witness and participate in the trial as their courtroom presence would have permitted. All that was denied them was the opportunity to influence the jury by the emotional impact of the children's presence or to distract the jury from the evidence in hope of a result-oriented verdict. The district court's order merely protected Respondent's right to a verdict based solely on the evidence without impeding either Petitioners' presentation of proof or their participation in their trial.

Certain Petitioners sued Respondent asserting private claims under the Food, Drug and Cosmetic Act. Having been unsuccessful at trial, they now attack the legal sufficiency of those claims, contending that their chosen forum lacked jurisdiction. They do not contend that their federal claims were frivolous but only mistakenly argue that *subsequent* decisions by this Court and the court of appeals declared such private claims unavailable under the FDCA. However, the availability of such private FDCA claims is an open question, as it was when Petitioners' federal claims were filed. In any event, the supposed legal insufficiency of Petitioners' federal claims does not destroy the subject matter jurisdiction of the district court.

III. ARGUMENT

A. SEPARATE TRIAL OF THE QUESTION WHETHER BENDECTIN CAUSES BIRTH DEFECTS WAS CONDUCIVE TO EXPEDITION AND ECONOMY, AVOIDED PREJUDICE TO ANY PARTY AND WAS WITHIN THE DISCRETION OF THE DISTRICT COURT.

Petitioners seek a ruling not merely that "trifurcation" was unfair in their case, but that it is *always* unfair. They urge that the dangerous character of a product is not an issue that may *ever* be separately tried in a fair and just manner. In effect, Petitioners ask a modification of Rule 42(b), Fed. R. Civ. P. which permits any "separate issue" to be tried separately in the trial court's discretion. To the extent to which it is based other than on mischaracterization of the record, Petitioners' argument lends no support to their broad proposition and, in this case, confirms the wisdom of the procedure chosen by the district court and approved by the court of appeals.

Petitioners still maintain that no "fact witnesses," as opposed to expert witnesses, were permitted to testify. The court of appeals found this argument unsupported by the record. (Appendix to Petition, pp. 55A, 56A.) It was always contemplated by all concerned that the initial phase of trial would not focus on the circumstances of the individual plaintiffs. Without this understanding, Respondent's agreement, at Petitioners' request, to postpone any discovery regarding the majority of the plaintiffs (who joined the lawsuit after the discovery stay of August 30, 1984) would have been unthinkable. When, despite the discovery stay, plaintiffs announced their intention that their expert witness, Dr. Alan K. Done, display certain plaintiffs to the jury by way of explanation of his opinion, Respondent sought an order *in limine* precluding such testimony. The district court *denied this motion,* but the Petitioners never offered such testimony at trial.

Petitioners *never* disclosed even a desire that the first trial phase focus on the individual circumstances of each of over 1000 children. This limitation permitted and encouraged the majority of the Petitioners to join the consolidated case after the trifurcation order was entered.

Petitioners imply that photographs or representations of the birth defects at issue were excluded from evidence by the court. This is simply untrue. As the court of appeals noted:

> In this case, Plaintiffs correctly observe that there was no evidence admitted as to the physical condition of individual Plaintiffs. However, that was not because the judge was unwilling to let it in. At trial, attorney Chesley [PLCC Chiarman] recognized that he was not precluded from introducing photographs, diagrams, or skeletons.

Appendix to Petition, pp. 72-73.

There was never an *offer* of any evidence of the personal circumstances or history of any Petitioner or of any particular plaintiff's defects. Though the issue never arose at trial, admission of such evidence would likely have been prejudicial to the Respondent, because of the agreed stay on discovery. Respondent knew literally nothing about the majority of the Petitioners who had joined the consolidated action after August 30, 1984. It did not know whether the mother had taken Bendectin (or when) nor whether the family had a history of genetically-caused defects. Petitioners' failure to offer evidence concerning individual plaintiffs, even after the district court had refused to preclude it, reflected a tacit understanding of the scope of the trial's first phase. The arrangement was hardly one-sided. It was because the trial format permitted new plaintiffs to join the action without any change in trial strategy or tactics *by either side* and without any discovery by the Respondent that the numbers of plaintiffs grew so prodigiously up to and even during the trial.

The filing chronology indicates that Petitioners' counsel were beating the bushes to enlist as many plaintiffs as possible

to join in the trifurcated trial and, thus, to have the benefit of a judgment in their favor that Bendectin causes birth defects. Respondent was subject to suit in any state where Bendectin allegedly caused an injury. Only some two hundred Petitioner families were Ohio citizens. Why did the more than eight hundred Petitioner families flock to Ohio rather than file their cases at home? They did so because they considered the "trifurcated" Bendectin trial to be a gold mine and wanted to stake their claims. They now regret their decision because the verdict was against them.

Petitioners' assertion that the trial was characterized by a "sterile, laboratory type atmosphere" and by "inappropriate abstraction" is explained by the remainder of their petition. They bemoan the fact that they were not permitted to show that Bendectin causes birth defects by attempting to prove that the Respondent is an evil company. Petitioners were not permitted to try the Respondent for its association (as a licensee of an European company) with the sensational Thalidomide episode or for alleged misdeeds with respect to drugs *other than Bendectin*. Petitioners' objection to "sterility" is that they were forbidden to introduce the contamination of evidence which, though unrelated to causation, might induce the jury to endorse otherwise inadequate proof on causation. The very arguments of Petitioners against trifurcation demonstrate that the district court knew its business in separately trying Bendectin's safety. Not only did trifurcation avoid prejudice to Petitioners, it prevented that prejudice against Respondent which Petitioners' trial team stood ready to foment in the jury. Furthermore, as the court of appeals noted: "If anything, the narrowing of the range of inquiry through trifurcation substantially improved the manageability of the presentation of proofs by both sides and enhanced the jury's ability to comprehend the causation issue." (Appendix to Petition, p. 51.)

Petitioners finally criticize the use by the court of appeals of the phrase "undue prejudice" in evaluating the discretionary decision of the district court. Even the dissenting

panel member who raised this issue concurred with the majority that the district court's order of "trifurcation" was within its discretion. (Appendix to Petition, p. 77) Respondent urges that the panel below was unanimous in its reasoning on trifurcation as well as its conclusion. The phrase "undue prejudice," like "unfair prejudice," as used in Federal Evidence Rule 403, is hardly meant to suggest that some lesser degree of prejudice is "due" or "fair." The sense of the majority opinion, like that of the dissent, is that *no* prejudice was inflicted by the trifurcation order.

B. THE DISTRICT COURT'S DECISION TO LIMIT PLAINTIFFS OF TENDER YEARS AND THOSE VISIBLY DEFORMED TO TELEVISION VIEWING OF THE TRIAL REASONABLY BALANCED THE RIGHTS OF PETITIONERS WITH THOSE OF RESPONDENT.

All minor Petitioners who were able to come (or be carried) to the courthouse were allowed to see and hear *the entire trial* and to talk with their counsel during trial. An unknown few were limited to doing so by means of closed circuit television and a telephone hook up. This very significant fact is omitted from the petition. Petitioners do not contend that this arrangement was at all inferior to physical courtroom presence as a means to provide to their counsel such information or assistance as these children had to give. The only benefit of courtroom attendance which was denied any Petitioner was a chance for the jury to see them during trial, and alternate its attention between them (and their physical defects) and the evidence being presented. This trial did not concern the extent of Petitioners' injury nor even whether Bendectin had caused *these particular* injuries. No evidence was *offered* of any Petitioner's injury or history, even by photographs. No Petitioner was offered as a witness, including any parent or guardian. Only their claim that Bendectin was an injury-causing product was, as yet, on trial.

Thus, the only "right" which Petitioners can claim to have been denied is the "right" to sway the jury's fact-finding by that sympathy which deformed or crippled children invariably arouse or to distract the jury from the evidence. Who among the Petitioners wished to exercise these supposed "rights" is undiscoverable from the record.

Petitioners cannot show who among them is personally aggrieved by the exclusion order, that is, who would have attended the trial in the courtroom, but for the order. They cannot say who wished to attend, or could have attended. Most voluntarily consolidated their suits for trifurcated trial after the district court had declared on the record its intention to exclude children too young to assist counsel. Such statement predated even the trifurcation order. This fact and the "random selection" proposal advanced by the PLCC when the district court's intention was revealed, (discussed at page 8, above) shows that few, if any, plaintiff children would have attended. To have identified those children able and desirous of attending would, of course, also have identified the remainder (and majority) as free of any practical impact from the order, and denied those absentees the benefit of this claim of constitutional error. To have standing to appeal, any Petitioner must show "distinct and palpable injury to himself." *Warth* v. *Selden*, 422 U.S. 490, 501 (1975).

Petitioners imply that they *all* deserve a new trial because of the exclusion order. However, no parent or guardian was excluded from the trial (though few attended) nor was any child who was at least 10 years old excluded, save those with visible defects. There is no logic in contending that a party who was not excluded is entitled to a new trial because others were excluded wrongfully. At most, only those unlawfully excluded can rely upon this claim of constitutional error.

Petitioners complain that the district court's exclusion order was entered without a hearing at which the excluded children were heard and seen by the court. However, they neither asked for a hearing for this purpose nor offered any evidence that the court's fears of prejudice or disruption were un-

founded. Allowing a scant 15 minutes per child, 36 trial days or about 7 weeks would be needed for hearings on the 1000 living plaintiff children. Of course, presumably fewer than that were afflicted with visible birth defects or under 10 years old at the time of trial.

However, this was as unnecessary as it was impractical. Only those able and wishing to attend needed a hearing of any sort. As noted, these individuals cannot be identified. This information is not only necessary to a determination of who might have been prejudiced by the order; it is necessary to knowing who was affected *at all*. Both the Petitioners and the dissenting judge in the court of appeals ignored the impossibility of determining, on this record, who among Petitioners would even have standing to claim a new trial by reason of the exclusion order. Petitioners alone could have created such a record and declined to do so.

Since Petitioners ask for a retrial based upon the exclusion order, it is worth considering how the district court might handle the exclusion issue on retrial. Respondent would, of course, maintain, as it did before, that the children cannot help their case (or their counsel) other than by enlisting the jury's sympathy, and that those with visible deformities would influence the jury to decide the case on a basis other than the evidence. The conduct of the "hearing" which Petitioners only now demand would pose numerous theoretical questions in anticipation of a new trial. If any particular child were deemed excludable at a retrial, would there be any reason for a retrial as to his claims? If a child plaintiff is found not excludable at retrial but declines (or is otherwise unable) to attend, does the retrial of his case serve any purpose other than to give him a second bite at the apple?

Petitioners claim that unknown and unidentified children were denied their "due process" rights to a fair trial. They do *not* urge that they were denied the right to witness the trial or to assist counsel (assuming, without support in the record, that they had the capacity to assist). Whoever these children were, they had the means to do *both*. All that was denied was

the chance to have the jury see such children as a focus for sympathy, not as witnesses or as human demonstrative evidence (neither of which was attempted).

Petitioners misreport the outcome of *Helminski* v. *Ayerst Laboratories*, 766 F. 2d 208 (6th Cir. 1985), *cert. denied*, 474 U.S. 981 (1985), maintaining that it stands for the proposition that exclusion of a plaintiff without a hearing at which he is seen and heard by the court mandates reversal and new trial. In fact, the Sixth Circuit in *Helminski* found that such a hearing was called for (and erroneously denied the minor plaintiff there), but nonetheless *affirmed* the defense judgment (Appendix to Petition, pages 69-70a). The court held that the inability of the minor plaintiff to comprehend the proceedings in his case or to assist counsel warranted the conclusion that his absence had not affected the outcome. A strict application of the principles of *Helminski* to this case would warrant affirmance of the defense judgment.

In considering Petitioner's motion for new trial, the district court specifically inquired of their counsel whether the presence of any minor plaintiff in the courtroom would have aided the presentation of the case. Petitioners' counsel declined to even argue (let alone attempt to demonstrate) that such was possible. Asked the same question by the court of appeals, Petitioners' counsel argued that "the one thing that the plaintiffs could have supplied had they been present would have been 'the humanistic aspect of this litigation' not that they would have been able to aid or assist counsel." Appendix to Petition, p. 72. Petitioners do not suggest that the presence of any child could have influenced the jury's fact finding other than by giving it a nonevidentiary basis for its verdict, or that a retrial with the children in attendance would change the outcome other than through the influence of sympathy on the jurors' minds.

While it is settled that children in our society possess civil rights, among them that to due process, it is also settled that, in many respects, these rights may be limited or abridged by reason of age. The right to vote, to hold office and, most im-

portantly, *to sue* is denied to infants. The right to petition the courts for relief is, more accurately, consigned to the parent or guardian of the minor during his minority. In this sense, children may be kept, not only from the courtroom, but from the courthouse by their age. It is fully consistent with fairness that the parent, also entrusted with the child's need for shelter, food, clothing and nurturing, should manage his legal affairs. No one can doubt that the parents of these minor plaintiffs were better able than they to oversee the trial of their claims. No such parent was excluded from the courtroom.

By the electronic means which the district court employed, all Petitioners were able to witness the trial as it occurred and consult with their counsel simultaneously. In a limited trial in which the individual condition of Petitioners was neither a relevant fact nor (in most cases) open to pretrial discovery, the district court respected and preserved Petitioners' practical rights as parties while preventing the risk of a result-oriented verdict. No party was prejudiced by the district court's action.

C. A PLAINTIFF WHO FILES A NON-FRIVOLOUS FEDERAL CLAIM IN FEDERAL COURT MAY NOT, HAVING LOST THE TRIAL WHICH HIS PLEADING DEMANDED, DESTROY SUBJECT MATTER JURISDICTION BY THEREAFTER CONTENDING THAT THE FEDERAL STATUTE ON WHICH HE SUED PROVIDES FOR NO PRIVATE CLAIMS.

All Petitioners who rely upon the Petition's third question of law invoked federal jurisdiction by filing claims against Respondent in federal court, specifically alleging that subject matter jurisdiction was present. As the court of appeals found, *and as these Petitioners do not deny*, "a straight forward reading of plaintiffs' complaint gives the undeniable impression that plaintiffs intended to allege an implied cause of

action under FDCA."[11] The issue of Petitioners' third question is, then, whether a complaint stating an implied cause of action under the Food, Drug and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq. (1982 ed., Supp. II) was sufficient to vest subject matter jurisdiction in the district court.

In this case, neither the district court nor the court of appeals reached any determination as to whether private claims under the Food, Drug and Cosmetic Act were available. It was simply not necessary to reach that issue before the initial phase of trial. Most plaintiffs had invoked jurisdiction based upon diversity of citizenship which was undisputedly present. The trial would go forward, on schedule, regardless of what additional plaintiffs sought consolidation of their claims, because all plaintiffs were united in their objective to demonstrate to the jury that Bendectin causes birth defects. Neither was the availability of private FDCA claims resolved in either of the precedent decisions upon which the Petitioners exclusively rely, i.e. *Merrell Dow Pharmaceuticals, Inc.* v. *Thompson*, 478 U.S. 804 (1986), or *Thompson* v. *Merrell Dow Pharmaceuticals, Inc.*, 766 F.2d 1005 (6th Cir. 1985).

In the *Thompson* cases, the issue was never reached because, *from the beginning*, no party contended that such private claims were available. *Thompson* concerned citizens of Canada and Scotland who sued Respondent in state court. Other foreign nationals similarly situated had seen the dismissal of their Bendectin lawsuits in federal court on the basis of *forum non conveniens*. Because the *Thompson* plaintiffs desired the advantages of an American forum, they

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[11] In addressing the Petitioners' jurisdictional objection in the court of appeals, Merrell Dow identified 15 Petitioner families in whose cases neither diversity of citizenship nor "federal question" jurisdiction could be demonstrated. Respondent therefore conceded, in the court of appeals, that the district court lacked jurisdiction over the claims of these plaintiffs, who are identified on page 6 of the appendix to the petition. The comment in the body of the petition that the defendant had "concealed [rather than "conceded"] that the district court was without jurisdiction to render judgment" in such cases is clearly a typographical error.

postured themselves to defeat federal jurisdiction on removal. Respondent, as a resident of the forum state, could not remove the actions based on alienage, but only based upon a claim arising under federal law. Though the *Thompson* plaintiffs had alleged violations of the FDCA and damages resulting therefrom, they maintained that these federal allegations were pled solely as elements of state created claims. Since Respondent, as a pharmaceutical manufacturer, was unwilling to contend that the FDCA permitted private claims, it did not there dispute plaintiffs' posture that they had pled only state law claims. Rather, it removed the actions on the premise that the non-federal claims of the plaintiffs "necessarily depended" on the FDCA violations which they alleged.

No party in the *Thompson* cases argued, before *any* court, that the FDCA implied the availability of private claims for violations of the statute. Neither the district court, the court of appeals nor *this Court* had the necessity or opportunity to decide whether such private claims were available. There was simply no controversy on the point.

The rationale for the decision of the court of appeals in *Thompson* was briefly stated:

> The parties agree that the FDCA does not create or imply private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief depended necessarily on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. [Citations omitted.]

766 F.2d at 1006.

The court of appeals in *Thompson* did *not* reach any conclusion[12] on whether the FDCA creates, by implication, a private right of action for violations. It did not and could not there consider the situation in which a plaintiff, as did Petitioners, expressly invokes federal jurisdiction by pleading claims under the FDCA. Though this Court affirmed the decision of the court of appeals in *Thompson*, it did so pursuant to a very different analysis[13] and, in fact, rejected the reasoning employed by the court of appeals.

> Petitioner also contends that the Court of Appeals' opinion rests on a view that federal question jurisdiction was inappropriate because, whatever the role of the federal issue in the FDCA-related count, the plaintiff could recover on other, strictly state law claims. *See* 766 F.2d at 1006 (noting that "the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA"). To the extent that the opinion can be read to express such a view, we agree that it was erroneous. If the FDCA-related count presented a sufficient federal

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[12] The opinion of this Court in *Merrell Dow* v. *Thompson* echoes the observation of the court of appeals that the parties therein agreed that the FDCA created no private cause of action. However, this Court's opinion suggests that the court of appeals in that case did something more. "In this case, both parties agree with the court of appeals' *conclusion* that there is no federal cause of action for FDCA violations. For purposes of our decision, we *assume* that this is a correct interpretation of the FDCA." 106 S.Ct. at 3234 (emphasis added). However, the Sixth Circuit, in fact, reached no "conclusion" regarding the availability of private FDCA claims. Like this Court, it merely noted the lack of controversy on the point between the parties to that litigation.

[13] This court in *Thompson assumed*, based on the parties self-serving agreement, a congressional decision to preclude private FDCA claims. It held that to sustain "federal question" jurisdiction over a non-federal claim by reason of an essential federal element of that claim, (an alleged FDCA violation) would offend the implied will of Congress, *so assumed*. 106 S.Ct. at 3234. This Court never considered the *actual* will of Congress or the actual availability of private FDCA claims.

> question, its relationship to the other, state law claims would be determined by the ordinary principles of pendent jurisdiction described in *Mine Workers* v. *Gibbs*, 383 U.S. 715 (1966). For the reasons that we have stated, however, there is no federal question jurisdiction even with that possible error corrected.

Merrell Dow Pharmaceuticals, Inc. v. *Thompson*, 478 U.S. 894, 106 S.Ct. 3229, 3237 at footnote 15.

The fact that this Court made an assumption rather than a ruling on the availability of private FDCA claims is reinforced by the dissent:

> It bears emphasizing that the court does not hold that there is no private cause of action under the FDCA. Rather, it expressly states that "for purposes of our decision, we assume that this is a correct interpretation of the FDCA." Ante at 810. The court simply holds Petitioner to its concession that the FDCA provides no private remedy, and decides Petitioner's claim on the basis of this concession. I shall do the same . . .

106 S.Ct. 3229, 3241, footnote 4.

In *Merrell Dow* v. *Thompson*, the parties did concur, based upon their separate circumstances making that position expedient, that the FDCA provides no private claim. With the instant case in its present posture, Petitioners lately assert that no private claim is available, though they improperly cite to this Court's decision in *Thompson* for a *ruling* to that effect that was never made. Respondent as always, agrees that the FDCA provides no private claim. However, unlike the *Thompson* plaintiffs, Petitioners here expressly invoked federal subject matter jurisdiction based upon the premise (which they only *now* renounce) that the FDCA *does* provide a private claim. What prompts Petitioners' current "concession" is the fact that they have tried and lost a lawsuit in a forum which, but for their private FDCA claims, would have no jurisdiction. A plaintiff ought not be permitted to undo a

judgment against him merely by disavowing the sufficiency of his statutory claim which supports jurisdiction.

This is not a case in which this Court can decide whether private FDCA claims *are* available. Because of the trial's outcome, Petitioners are unwilling to here champion their own causes of action. The jurisdictional issue is whether Petitioners' now abandoned reliance on private FDCA claims in originally invoking federal jurisdiction was enough to trigger that jurisdiction. Respondent urges that it was.

In *Mt. Healthy City Board of Education* v. *Doyle*, 429 U.S. 274 (1976), this Court sustained subject matter jurisdiction under 28 U.S.C. § 1331 over a civil claim premised on violations of the First and Fourteenth Amendments and of federal civil rights statutes. This court found no *need* to decide either whether the Fourteenth Amendment provides a private cause of action for violations or whether the plaintiff had stated a sufficient claim under 28 U.S.C. 1983. This court expressly held that such issues *were not jurisdictional questions*:

> The question of whether the Board's argument should prevail, or whether as respondent urged in oral argument, we should, by analogy to our decision in *Bivens* v. *Six Unknown Fed. Narcotics Agents*, 403 U.S. 388 (1971), imply a cause of action directly from the Fourteenth Amendment which would not be subject to the limitations contained in Section 1983, is one which has never been decided by this Court. Counsel for respondent at oral argument suggested that it is an extremely important question and one which should not be decided on this record. We agree with respondent.
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> The Board has raised this question for the first time in a document filed after its reply brief in this Court. *Were it in truth a contention that the district court lacked jurisdiction, we would be obliged to consider it, even as were are obliged to inquire sua sponte whenever a doubt arises as to the existence of federal jurisdiction. Liberty Mutual Ins. Co.* v. *Wetzel*, 424 U.S. 737, 740 (1976); *Louisville & Nashville R. Co.* v. *Mottley*, 211 U.S. 149,

> 152 (1908). And if there were a § 1983 action, brought under the special jurisdictional provision of U.S.C. § 1343 which requires no amount in controversy, it would be appropriate for this Court to inquire, for jurisdictional purposes, whether a statutory action had in fact been alleged. *City of Keosha* v. *Bruno, supra. However, where an action is brought under § 1331, the catchall federal-question provision requiring in excess of $10,000.00 in controversy, jurisdiction is sufficiently established by allegation of a claim under the Constitution or federal statutes, unless it "clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction . . ."* *Bell* v. *Hood*, 327 U.S. 678, 682 (1946); *Montana-Dakota Utilities Co.* v. *Northwestern Pub. Serv. Co.*, 341 U.S. 246, 249 (1951).
>
> Here, respondent alleged that the Board had violated his rights under the First and Fourteenth Amendments and claimed the jurisdictionally necessary amount of damages. The claim that the Board is a "person" under § 1983, even assuming that correctness of the Board's argument that the § 1331 action is limited by the restrictions of § 1983, is not so patently without merit as to fail the test of *Bell* v. *Hood, supra. Therefore, the questions as to whether the respondents stated a claim for relief under § 1331 is not of the jurisdictional sort which the Court raises on its own motion.* The related question of whether a school district is a person for purposes of § 1983 is likewise not before us. We leave those questions for another day, and assume, without deciding, that the respondent could sue under § 1331 without regard to the limitations imposed by 42 U.S.C. § 1983.

429 U.S. at 278, 279 (emphasis added). The Second Circuit rejected a similar argument by another unsuccessful defendant in *Fogel* v. *Chestnutt*, 668 F.2d 100 (2d Cir. 1981), *cert. denied sub. nom. Currier* v. *Fogel*, 459 U.S. 828 (1981). There, the defendant-appellants argued that a private claim was unavailable under the federal statute upon which plain-

tiff had sued, excusing their failure to previously raise the issue by deeming it "jurisdictional." Rejecting this excuse, the court of appeals distinguished the question whether a federal cause of action states a claim upon which relief can be granted from the question whether such cause of action is insubstantial in a jurisdictional sense.

> This argument is simply one more instance of the fallacy, to which courts as well as counsel have not been immune, of confusing the question of whether a court has jurisdiction with the question of whether a complaint states a claim upon which relief can be granted.
>
> The complaint based jurisdiction on the ICA as well as the Investment Advisors Act of 1940 and the Securities Exchange Act of 1934. It thus stated a claim arising under a law of the United States, of which the district court has jurisdiction under 28 U.S.C. § 1331(a), as well as § 44 of the ICA. *If in fact the statutes relied upon by the plaintiffs did not authorize recovery of damages because of violations of the sort alleged, the complaint failed to state a claim upon which relief could be granted and was subject to dismissal on that ground. However, as defendants would have been the first to assert if they had prevailed in that position and plaintiffs brought another action for the same relief, the dismissal would have been upon the merits and not for lack of jurisdiction.*
>
> Jurisdiction, therefore, is not defeated as respondents seem to contend, by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. *For it is well settled that the failure to state a proper cause of action calls for judgment on the merits and not for a dismissal for want of jurisdiction.* Whether a complaint states a cause of action on which relief could be granted is a question of law and just as issues of fact must be decided after and not before the court has assumed jurisdiction over the controversy. If the court does later exercise its jurisdiction to

> determine that the allegations in the complaint do not state a ground for relief, then dismissal of the case would be on the merits, not for want of jurisdiction. *Swafford* v. *Templeton*, 185 U.S. 487, 493, 494, 22 S. Ct. 783, 785, 786, 46 L. Ed. 1005; *Binderup* v. *Taft Exchange*, 263 U.S. 291, 305-308, 44 S. Ct. 96, 98-99, 68 L. Ed. 308. The previously carved out exceptions are that a suit may sometimes by dismissed for want of jurisdiction *where the alleged claim under the constitution or federal statutes clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or where such a claim is wholly insubstantial and frivolous.*

668 F.2d at 105, 106 (emphasis added). Had the jury found *against* it, Respondent might now argue the jurisdictional position of the petitioner in *Mt. Healthy* and of the appellant in *Fogel*, though it would meet with no greater success. Likewise, had the plaintiffs in those cases *lost* at trial, the supposed legal insufficiency of their federal statutory claims would have been no more of a jurisdictional shield in their hands than it was when the defendants in those cases invoked it as such. So it is with Petitioners' jurisdictional objection.

This court in *Mt. Healthy* and the Second Circuit in *Fogel* recognized that a federal claim will sustain jurisdiction under 28 U.S.C. § 1331 unless it "clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction . . ." *Bell* v. *Hood*, 327 U.S. 678 (1946). This is true regardless of whether it states a claim upon which relief can be granted.[14] Petitioners' FDCA claims were not frivolous,

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[14] The reason why this two-tiered analysis tends, in practice, to become blurred is that separate decisions on legal sufficiency as opposed to jurisdictional sufficiency are, in many cases, practically indistinguishable to the parties. An appropriate example is the decision of the district court in *Griffin* v. *O'Neal, Jones & Feldman, Inc.*, 604 F. Supp. 717 (S.D. Ohio 1985). In *Griffin*, decided by the district court shortly *after* the jury verdict in the instant case, plaintiffs brought claims nearly identical to those in the instant case though they concerned a different drug. Such included claims for negligence, breach of warranty, strict liability, FDCA violations, "fraud"

though Respondent still maintains that they were legally insufficient. As late as this Court's decision in *Thompson* (well after the trial below) the availability of private FDCA claims was an open question and continues to be such. Accordingly, Petitioners' claims conferred subject matter jurisdiction on the district court.

The legal insufficiency of the Petitioners' FDCA claims, like many other substantive defenses advanced by the Respondent but never ruled upon, were deferred by the district court to permit trial of the common question whether Bendectin causes human birth defects. This issue was an essential one to all the claims of all the Petitioners and no less to their claims under the FDCA. There was no *adjudication* of the claims under the FDCA prior to the jury verdict, since the court, in an effort to expedite the progress of a mass tort litigation by trial of its single universal issue, found no need to reach this *non jurisdictional* question before trial.

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and a separate claim for punitive damages. The district court dismissed the federal claims *on their merits* under Rule 12(b)(6), Fed. R. Civ. P., 604 F. Supp. at 718. The non-federal claims were then dismissed without prejudice under *United Mine Workers* v. *Gibbs*, 383 U.S. 715, 86 S. Ct. 2130, 16 L. Ed. 2d 218 (1966), since they had been "orphaned" by *pre-trial* dismissal of the federal claims on which jurisdiction depended. There can be no doubt, however, that the federal claims, themselves, were *adjudicated on their merits*. Had the plaintiffs in *Griffin* refiled their FDCA and RICO claims in state court, the defendants would have the complete defense of *res judicata* by reason of the district court's decision. *Cannon* v. *Loyola University of Chicago*, 609 F. Supp. 1010, 1015 (N.D. Ill. 1985), *aff'd*, 784 F.2d 777 (7th Cir. 1986). It happens that the Plaintiffs in *Griffin* were represented by counsel for Petitioners, Mr. Chesley.

IV. CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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